TITLE 180 CONTROL OF RADIATION

CHAPTER 20 THERAPEUTIC RADATION MACHINES

APPENDIX

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CHAPTER 20 THERAPUTIC RADIATION MACHINES

20-001 SCOPE AND AUTHORITY

20-001.01 180 NAC 20 provides special requirements for therapeutic radiation machines. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 3520.

20-001.02 The requirements of this 180 NAC 20 are in addition to, and not in substitution for applicable requirements in 180 NAC 1, 2, 3, 4, 6, 10, 15, 17 and 18.

20-002 DEFINITIONS: As used in 180 NAC 20, the following definitions apply:

Absorbed dose rate means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

Air kerma (K) means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE, where dE is the sum of the initial kinetic energies of all ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

Barrier (See “Protective barrier”).

Beam axis means the axis of rotation of the beam limiting device.

Beam-limiting device means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimension of the useful beam.

Beam monitoring system means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

Beam scattering foil means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

Bent beam linear accelerator means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

Contact therapy system means a therapeutic machine with a short target to skin distance (TSD), usually less then 5 centimeters.

Detector (See Radiation detector).

Dose Monitor Unit (DMU) means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

External beam radiation therapy means therapeutic irradiation in which the source of radiation is at a distance from the body.

Field-flattening filter means a filter used to homogenize the absorbed dose rate over the radiation field.

Filter means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to 180 NAC 20-006.

Gantry means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

Interlock means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

Interruption of irradiation means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

Irradiation means the exposure of living being or matter to ionizing radiation.

Isocenter means the center of the sphere though which the useful beam axis passes while the gantry moves through it full range of motions.

Kilovolt (kVP)[kilo electron volt (keV)] means the energy equal to the acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. [Note: current convention is to use kV for photons and keV for electrons.]

Lead equivalent means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

Leakage radiation means radiation emanating from the radiation therapy system except for the useful beam.

Light field means that area illuminated by light, simulating the radiation field.

Megavolt (MV) [mega electron volt (MeV)] means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. [Note current convention is to use MV for photons and MeV for electrons.]

Misadministration means the administration of a Therapeutic Particle Accelerator Dose:

1. Involving the wrong patient or wrong treatment site;
2. When the treatment consists of three or fewer fractions and the calculated total absorbed dose administered differs from the total absorbed dose prescribed by more than ten percent of the total prescribed dose;
3. When the calculated weekly administered dose is 30 percent or more greater than the weekly prescribed dose; or
4. When the calculated total absorbed dose administered differs from the total absorbed dose prescribed by more than 20 percent of the total prescribed dose.

Monitor unit (MU) (See “Dose monitor unit”).

Moving beam radiation therapy means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

Nominial treatment distance means:

a. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.
b. For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance must be that specified by the manufacturer.

Patient means an individual subjected to machine produced external beam radiation for the purposes of medical therapy.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Periodic quality assurance check means a procedure which is performed to ensure that a previous calibration continues to be valid.

Phantom means an object behaving in essentially the same manner as tissue, with respect to the absorption or scattering of the ionizing radiation in question.

Primary dose monitoring system means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

Primary protective barrier see "Protective barrier".

Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam.
b. "Secondary protective barrier" means the material which attenuates stray radiation.

Radiation detector means a device which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation field see "Useful beam".

Radiation head means the structure from which the useful beam emerges.

Radiological Medical Physicist means an individual qualified in accordance with 180 NAC 15-013.01.

Redundant beam monitoring system means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

Scattered radiation means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

Secondary dose monitoring system means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

Secondary protective barrier see "Protective barrier".

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

Source means the region and/or material from which the radiation emanates.

Source-skin distance (SSD) see "Target-skin distance".

Stationary beam radiation therapy means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

Stray radiation means the sum of leakage and scattered radiation.

Target means that part of an X-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

Target-skin distance (TSD) means the distance measured along the beam axis from the center of the front surface of the X-ray target and/or electron virtual source to the surface of the irradiated object or patient.

Tenth-value layer (TVL) means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.Termination of irradiation means the stopping of irradiation in a fashion which will not permit continuance of

irradiation without the resetting of operating conditions at the control panel.

Therapeutic radiation machine means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

Tube means an X-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Useful beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

Virtual source means a point from which radiation appears to originate.

Wedge filter means a filter which effects continuous change in transmission over all or a part of the useful beam.

X-ray tube means any electron tube which is designed to be used primarily for the production of X-rays.

20-003 GENERAL ADMINISTRATIVE REQUIREMENTS FOR FACILITIES USING THERAPEUTIC RADIATION MACHINES

20-003.01 Administrative Controls The registrant will be responsible for directing the operation of the therapeutic radiation machines that have been registered with the Department. The registrant or the registrant's agent will ensure that the requirements of 180 NAC 20 are met in the operation of the therapeutic radiation machine(s).

20-003.02 A therapeutic radiation machine that does not meet the provisions of these regulations can not be used for irradiation of patients.

20-003.03 Training for External Beam Radiation Therapy Users The registrant of any therapeutic radiation machine subject to 180 NAC 20.006 or 20.007 must require the user to be a physician who is licensed in the State of Nebraska and who:

1. Is certified in:

   a. Radiology or therapeutic radiology by the American Board of Radiology; or
   b. Radiation oncology by the American Osteopathic Board of Radiology; or
   c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
   d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

2. Is in the active practice of therapeutic radiology, and has completed 200 hours of

instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience.

a. To satisfy the requirement for instruction, the classroom and laboratory training must include:

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of ionization radiation; and
(4) Radiation biology.

b. To satisfy the requirement for supervised work experience, training must be under the supervision of an individual meeting the requirements of 180 NAC 20-003.03 and must include:

(1) Review of the full calibration measurements and periodic quality assurance checks;
(2) Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
(3) Using administrative controls to prevent misadministrations;
(4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
(5) Checking and using radiation survey meters.

c. To satisfy the requirement for a period of supervised clinical experience, training must include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an individual meeting the requirements of 180 NAC 20-003.03. The supervised clinical experience must include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;
(2) Selecting proper dose and how it is to be administered;
(3) Calculating the external beam radiation therapy doses and collaborating with the user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and
(4) Post-administration follow-up and review of case histories.

20-003.04 Training for Radiological Medical Physicist The registrant for any therapeutic radiation machine subject to 20 NAC 20-006 or 20-007 must require the individual to meet the training requirements of 180 NAC 15-013.01.

20-003.05 Qualifications of Operators Individuals who will be operating a therapeutic radiation machine for medical use must be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists. Individuals who are not ARRT Registered Radiation Therapy Technologists must submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology.[1/]
20-003.06 Written safety procedures and rules must be developed by a Radiological Medical Physicist and must be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator must be able to demonstrate familiarity with these rules.

20-003.07 Individuals must not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

20-003.08 All individuals associated with the operation of a therapeutic radiation machine must be instructed in and must comply with the provisions of the registrant's quality management program. In addition to the requirements of 180 NAC 20, these individuals are also subject to the requirements of 180 NAC 4-005, 4-009 and 4-021.

20-003.09 Information and Maintenance Record and Associated Information The registrant must maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Department:

1. Report of acceptance testing;

2. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 180 NAC 20, as well as the name(s) of person(s) who performed such activities;

3. Records of maintenance and/or modifications performed on the therapeutic radiation machine, as well as the name(s) of person(s) who performed such services;

4. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

[1/] "Standards for Accredited Educational Program in Radiologic Sciences – Effective January 1, 2002", Joint Review Committee on Education in Radiologic Technology, January 1996; Revised 2001.

20-003.10 Records Retention All records required by 180 NAC 20 must be retained until disposal is authorized by the Department unless another retention period is specifically authorized in 180 NAC 20. All required records must be retained in an active file from the time of generation, until at least the next Department inspection. Any required record generated prior to the last Department inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Department authorizes final disposal.

20-004 GENERAL TECHNICAL REQUIREMENTS FOR FACILITIES USING THERAPEUTIC RADIATION MACHINES

20-004.01 Protection Surveys

1. The registrant must ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with 180 NAC 20-008. The radiation protection survey must be performed by, or under the direction of, a Radiological Medical Physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with and without a scattering phantom in the useful beam of radiation:

    a. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 180 NAC 4-005.01; and
    b. Radiation levels in unrestricted areas do not exceed the limits specified in Parts 180 NAC 4-013.01 and 180 NAC 4-013.02.

2. In addition to the requirements of 180 NAC 20-004.01, item 1, a radiation protection survey must also be performed prior to any subsequent medical use and:

    a. After making any change in the treatment room shielding;
    b. After making any change in the location of the therapeutic radiation machine within the treatment room;
    c. After relocating the therapeutic radiation machine; or
    d. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

3. The survey record must also include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey;

4. If the results of the surveys required by 180 NAC 20-004.01, item 1 or 2 indicate any radiation levels in excess of the respective limit specified in 180 NAC 20-004.01, item 1., the registrant must lock the control in the "OFF" position and not use the unit:

    a. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or
    b. Until the registrant has received a specific exemption from the Department.

20-004.02 Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program If the survey required by 180 NAC 20-004.01 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 180 NAC 4-013.01 and 4-013.02, before beginning the treatment program the registrant must:

1. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 180 NAC 4-013.01 and 4-013.02;

2. Perform the survey required by 180 NAC 20-004.01 again; and

3. Include in the report required by 180 NAC 20-004.04 the results of the initial survey, a description of the modification made to comply with 180 NAC 20-004.02, item 1, and the results of the second survey; or

4. Request and receive a registration amendment under 180 NAC 4-013.03 that authorizes radiation levels in unrestricted areas greater than those permitted by 180 NAC 4-013.01 and 4-013.02.

20-004.03 Dosimetry Equipment

1. The registrant must have a calibrated dosimetry system available for use. The system must have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration must have been performed within the previous 24 months and after any servicing that may have affected system calibration.

2. The dosimetry system must have been calibrated at an energy (energy range) appropriate for the radiation being measured;

3. The registrant must have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 180 NAC 20-004.03, item 1. This comparison will have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 180 NAC 20-004.03, item 1.

4. The registrant must maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the registration. For each calibration, intercomparison, or comparison, the record must include: the date; the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by 180 NAC 20-004.03, item 1. and 2.; the correction factors that were determined; the names of the individuals who performed the calibration, intercomparison, or comparison; and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a Radiological Medical Physicist.

20-005 QUALITY MANAGEMENT PROGRAM Each registrant or applicant subject to 180 NAC 20-006 or 20-007 must develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the user.

20-005.01 Scope and Applicability: The quality management program must address, as a minimum the following specific objectives:

1. Written Directives:

   a. A written directive must be dated and signed by a user prior to the administration of radiation. If because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and revised written directive is signed by an user within 48 hours of the oral revision.
   b. The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and the number of fractions.
   c. A written revision to an existing written directive may be made provided that the revision is dated and signed by an user prior to the administration of the external beam dose, or the next fractional dose.
   d. The registrant must retain a copy of the written directive for three years.

2. Procedures for Administration: The registrant must develop, implement, and maintain written procedures to provide high confidence that:

   a. Prior to the administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;
   b. Each administration is in accordance with the written directive;
   c. External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by:

      (1) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive;
      (2) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(3) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and
(4) The registrant retains a copy of the procedures for administration for the duration of the registration.

2-005.02 Reports and Notifications of Misadministrations

1. Other than events that result from intervention by a patient or human research subject, a registrant must report any event in which the administration of an external beam radiation dose:

   a. Involving the wrong patient, wrong treatment modality, or wrong treatment site; orb. When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or
   c. When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or
   d. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

2. The registrant must notify the Department by telephone nor later than the next business day after the discovery of a misadministration.

3. The registrant must submit a written report to the Department within 30 days after the discovery of a misadministration. The written report must include:

   a. The registrant's name;
   b. The name of the prescribing physician;
   c. A brief description of the event;
   d. Why the event occurred;
   e. The effect, if any on the individual(s) who received the administration;
   f. Actions, it any, that have been taken, or are planned to prevent recurrence;
   g. Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

4. The report may not contain the individual's name or any other information that could lead to the identification of the individual.

5. The registrant must provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant must make the appropriate notifications as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedical care as a result of the misadminstration,

because of any delay in notification. To meet the requirements of 180 NAC 20-005.02, item 5, the notification of the individual who is the subject of the misadminstration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant must inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the registrant upon request. The registrant must provide such a written description if requested.

6. Aside from the notification requirement, nothing in this section affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relative or guardians.

7. The registrant must retain a record of misadministration in accordance with 180 NAC 20-005.03. A copy of the record required must be provided to the referring physician if other than the registrant within 15 days after discovery of the misadministration.

20-005.03 Records of Misadministrations: A registrant must retain a record of misadministration reported in accordance with 180 NAC 20-005.02 for three years. The record must contain the following:

1. The registrant's name and the names of the individuals involved ;

2. The identification number, if one has been assigned, of the individual who is the subject of the misadministration;

3. A brief description of the event; why it occurred; the effect, if any, on the individual;

4. The actions, if any, taken or planned to prevent recurrence; and

5. Whether the registrant notified the individual (or the individual's responsible relative or guardian), and, if not, whether such failure to notify was based on guidance from the referring physician.

20-006 THERAPEUTIC RADIATION MACHINES OF LESS THAN 500 kV

20-006.01 Leakage Radiation When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate must not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. 0-50 kV Systems The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly must not exceed 1 mGy (100 mrad) in any one hour.

2. >50 and <500 kV Systems The leakage air kerma rate measured at a distance of 1 meter from the target in any direction must not exceed 1 cGy (1 rad) in any 1

hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly must not exceed 30 cGy (30 rad) per hour.

3. For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 180 NAC 20-006.01, item 1. and 2. for the specified operating conditions. Records on leakage radiation measurements must be maintained at the installation for inspection by the Department.

20-006.02 Permanent Beam Limiting Devices Permanent diaphragms or cones used for limiting the useful beam must provide at least the same degree of attenuation as required for the tube housing assembly.

20-006.03 Adjustable or Removable Beam Limiting Devices

1. All adjustable or removable beam limiting devices, diaphragms, cones or blocks must not transmit more than 5 percent of the useful beam for the most penetrating beam used;

2. When adjustable beam limiting devices are used, the position and shape of the radiation field must be indicated by a light beam.

20-006.04 Filter System The filter system must be so designed that:

1. Filters can not be accidentally displaced at any possible tube orientation;

2. For equipment installed after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot does not exceed 1 cGy (1 rad) per hour at 1 meter under any operating conditions; and

4. Each filter is marked as to its material of construction and its thickness.

20-006.05 Tube Immobilization

1. The X-ray tube must be so mounted that it can not accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly must be capable of being immobilized for stationary portal treatments.

20-006.06 Source Marking The tube housing assembly must be marked so that it is possible to determine the location of the source to within 5 millimeters, and such marking must be readily accessible for use during calibration procedures.

20-006.07 Beam Block Contact therapy tube housing assemblies must have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

20-006.08 Timer A suitable irradiation control device must be provided to terminate the irradiation after a pre-set time interval.

1. The timer, with a display, must be provided at the treatment control panel. The timer must have a pre-set time selector and an elapsed time or time remaining indicator;

2 The timer must be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it will be necessary to reset the elapsed time indicator;

3. The timer must terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer must permit accurate pre-setting and determination of exposure times as short as 1 second;

5. The timer must not permit an exposure if set at zero;

6. The timer must not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. The timer must be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

20-006.09 Control Panel Functions The control panel, in addition to the displays required by other provisions in 180 NAC 20-006, must have:

1. An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

2. An indication of whether X-rays are being produced;

3. A means for indicating X-ray tube potential and current;

4. The means for terminating an exposure at any time;

5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

6. For therapeutic radiation machines installed after **[**INSERT EFFECTIVE DATE OF THESE REGULATIONS], a positive display of specific filter(s) in the beam.

20-006.10 Multiple Tubes When a control panel may energize more than one X-ray tube:

1. It must be possible to activate only one X-ray tube at any time;

2. There must be an indication at the control panel identifying which X-ray tube is activated; and

3. There must be an indication at the tube housing assembly when that tube is energized.

20-006.11 Target-to-Skin Distance (TSD) There must be a means of determining the central axis TSD to within 1 centimeter and of reproducing this measurement to within 2 millimeters thereafter.

20-006.12 Shutters Unless it is possible to bring the X-ray output to the prescribed exposure parameters within 5 seconds after the X-ray "ON" switch is energized, the beam must be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter must be controlled by the operator from the control panel. An indication of shutter position must appear at the control panel.

20-006.13 Low Filtration X-ray Tubes Each therapeutic radiation machine equipped with a beryllium or other low-filtration window must be clearly labeled as such upon the tube housing assembly and must be provided with a permanent warning device on the control panel that is activated when no additional filtration is present.

20-006.14 Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV In addition to shielding adequate to meet requirements of 180 NAC 20-009, the treatment room must meet the following design requirements:

1. Aural Communication Provision must be made for continuous two-way aural communication between the patient and the operator at the control panel;

2. Viewing Systems Provision must be made to permit continuous observation of the patient during irradiation and the viewing system must be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine must not be used for patient irradiation unless at least one viewing system is operational.

20-006.15 Additional Requirements Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

1. All protective barriers must be fixed except for entrance doors or beam

interceptors;

2. The control panel must be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

3. Interlocks must be provided such that all entrance doors, including doors to any interior booths, must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it must not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

4. When any door referred to in 180 NAC 20-006.15, item 3. is opened while the X-ray tube is activated, the air kerma rate at a distance of 1 meter from the source must be reduced to less than 1 mGy (100 mrad) per hour.

20-006.16 Full Calibration Measurements

1. Full calibration of a therapeutic radiation machine subject to 180 NAC 20-006 must be performed by, or under the direct supervision of, a Radiological Medical Physicist:

   a. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
   b. At intervals not exceeding 1 year; and
   c. Before medical use under the following conditions:

      (1) Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled; and
      (2) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

   d. Notwithstanding the requirements of 180 NAC 20-006.16, item 1.c.:

      (1) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and
      (2) If the repair, replacement or modification does not affect all energies, full calibration must be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 180 NAC 20-006.16, item 1.c.(1).

2. To satisfy the requirement of 180 NAC 20-006.16, item 1., full calibration must include:

a. The calibration must be performed in accordance with the protocol published by the American Association of Physicist in Medicine, or a user submitted protocol having the prior approval of the Department, before the system is first used for irradiation of patients and thereafter at time intervals which do no exceed one year and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.
b. An independent verification by a third party medical physicist other than the person performing the calibration.

3. The registrant must maintain a record of each calibration for the duration of the registration. The record must include: the date of the calibration; the manufacturer's name, model number, and serial number for the therapeutic radiation machine if applicable; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the Radiological Medical Physicist responsible for performing the calibration.

20-006.17 Periodic Quality Assurance Checks

1. Periodic quality assurance checks must be performed on therapeutic radiation machines subject to 180 NAC 20-006, which are capable of operation at greater than or equal to 50 kV.

2. To satisfy the requirement of 180 NAC 20-006.17, item 1., quality assurance checks must meet the following requirements:

a. The registrant must perform quality assurance checks in accordance with written procedures established by the Radiological Medical Physicist.; and
b. The quality assurance check procedures must specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures must specify that the quality assurance check will be performed during the calibration specified in 180 NAC 20-006.16, item 1. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in 180 NAC 20-006.16, item 1., must be stated.

3. The cause for a parameter exceeding a tolerance set by the Radiological Medical Physicist must be investigated and corrected before the system is used for patient irradiation;

4. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Radiological Medical Physicist's quality assurance check procedures, the system must be recalibrated as required in 180 NAC 20-006.16, item 1.;

5. The registrant must use the dosimetry system described in 180 NAC 20-004.03,

item 2. to make the quality assurance check required in 180 NAC 20-006.17, item 2.;

6. The registrant must have the Radiological Medical Physicist review and sign the results of each radiation output quality assurance check within 1 month of the date that the check was performed;

7. The registrant must ensure that quality assurance checks of therapeutic radiation machines subject to 180 NAC 20-006 are performed at intervals not to exceed 1 month;

8. Notwithstanding the requirements of 180 NAC 20-006.17, item 6. and 7., the registrant must ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 180 NAC 20-006.17, item 6. and 7. have been performed within the 30 day period immediately prior to said administration;

9. To satisfy the requirement of 180 NAC 20-006.17, item 2., safety quality assurance checks must ensure proper operation of:

   a. Electrical interlocks at each external beam radiation therapy room entrance;
   b. The "BEAM-ON" and termination switches;
   c. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;
   d. Viewing systems;
   e. If applicable, electrically operated treatment room doors from inside and outside the treatment room;

10. The registrant must maintain a record of each quality assurance check required by 180 NAC 20-006.17 item 1. and 7. for 3 years. The record must include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name; model number and serial number for the instrument(s) used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

20-006.18 Operating Procedures

1. The therapeutic radiation machine must not be used for irradiation of patients unless the requirements of 180 NAC 20-006.16 and 20-006.17. have been met;

2. Therapeutic radiation machines must not be left unattended unless secured pursuant to 180 NAC 20-006.09, item 5.;

3. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices must be used;

4. The tube housing assembly must not be held by an individual during operation

unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder must wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

5. A copy of the current operating and emergency procedures must be maintained at the therapeutic radiation machine control console; and

6. No individual other than the patient must be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room must be protected by a barrier sufficient to meet the requirements of 180 NAC 4-005.

20-007 THERAPEUTIC RADIATION MACHINES – PHOTON THERAPY SYSTEMS (500 kV AND ABOVE) AND ELECTRON THERAPY SYTEMS (500 keV and ABOVE)

20-007.01 Leakage Radiation Outside the Maximum Useful Beam In Photon and Electron Modes

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius 2 meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), must not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

2. Except for the area defined in 180 NAC 20-007.01, item 1., the absorbed dose due to leakage radiation (excluding neutrons) at 1 meter from the electron path between the electron source and the target or electron window must not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters;

3. For equipment manufactured after the effective date of these regulations, the neutron absorbed dose outside the useful beam must not exceed manufacturer's specifications. and

4. For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 180 NAC 20-007.02, items 1. through 3. for the specified operating conditions. Records on leakage radiation measurements must be maintained at the installation for inspection by the Department.

20-007.02 Leakage Radiation Through Beam Limiting Devices

1. Photon Radiation All adjustable or interchangeable beam limiting devices must attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) must not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten centimeter by ten centimeter radiation field;

2. Electron Radiation All adjustable or interchangeable electron applicators must attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance must not exceed:

   a. A maximum of two percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit must apply beyond a line seven centimeters outside the periphery of the useful beam; and
   b. A maximum of ten percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit must apply beyond a line two centimeters outside the periphery of the useful beam.

20-007.03 Measurement of Leakage Radiation.1. Photon Radiation. Measurements of leakage radiation through the beam limiting devices must be made with the beam limiting devices closed and any residual aperture blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set must be measured independently at the depth of maximum dose. Measurements must be made using a radiation detector of area not exceeding ten square centimeters;

2. Electron Radiation. Measurements of leakage radiation through the electron applicators must be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements must be made using one centimeter of water equivalent build up material.

20-007.04 Filters/Wedges

1. Each wedge filter that is removable from the system must be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle must appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor must be redetermined;

2. If the absorbed dose rate information required by 180 NAC 20-007.01 relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter must be removable only by the use of tools;

3. For equipment installed after [INSERT EFFECTIVE DATE OF THESE REGULATIONS] which utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

    a. Irradiation must not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;
    b. An interlock system must be provided to prevent irradiation if the filter selected is not in the correct position;
    c. A display must be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and
    d. An interlock must be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

20-007.05 Stray Radiation in the Useful Beam For equipment installed after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], the registrant must determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam do not exceed manufactures specification.

20-007.06 Beam Monitors All therapeutic radiation machines subject to 180 NAC 20-007 must be provided with redundant beam monitoring systems. The sensors for these systems must be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. Equipment installed after [INSERT EFFECTIVE DATE OF THESE REGULATIONS] must be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

2. Equipment installed on or before [INSERT EFFECTIVE DATE OF THESE REGULATIONS] must be provided with at least one radiation detector. This detector must be incorporated into a useful beam monitoring system;

3. The detector and the system into which that detector is incorporated must meet the following requirements:

    a. Each detector must be removable only with tools and, if movable, must be interlocked to prevent incorrect positioning;
    b. Each detector must form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;
    c. Each beam monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation; and

d. For equipment installed after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], the design of the beam monitoring systems must ensure that the:

(1) Malfunctioning of one system must not affect the correct functioning of the other system(s); and
(2) Failure of either system must terminate irradiation or prevent the initiation of radiation.

e. Each beam monitoring system must have a legible display at the treatment control panel. For equipment installed after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], each display must:

(1) Maintain a reading until intentionally reset;
(2) Have only one scale and no electrical or mechanical scale multiplying factors;
(3) Utilize a design such that increasing dose is displayed by increasing numbers; and
(4) In the event of power failure, the beam monitoring information required in 180 NAC 20-007.06, item 3.e.(3) displayed at the control panel at the time of failure must be retrievable in at least one system for a 20 minute period of time.

20-007.07 Beam Symmetry

1. Bent-beam linear accelerators subject to 180 NAC 20-007 must be provided with auxiliary device(s) to monitor beam symmetry;

2. The device(s) referenced in 180 NAC 20-007.07, item 1. must be able to detect field asymmetry greater than 10 percent; and

3. The device(s) referenced in 180 NAC 20-007.07, item 1. must be configured to terminate irradiation if the specifications in 180 NAC 20-007.07 item 2. can not be maintained.

20-007.08 Selection and Display of Dose Monitor Units

1. Irradiation must not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

2. The pre-selected number of dose monitor units must be displayed at the treatment control panel until reset manually for the next irradiation;

3. After termination of irradiation, it must be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

4. For equipment installed after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], after termination of irradiation, it must be necessary for the

operator to reset the pre-selected dose monitor units before irradiation can be initiated.

20-007.09 Air Kerma Rate/Absorbed Dose Rate For equipment installed after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], a system must be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in 180 NAC 20-007.06 may form part of this system. In addition:

1. The dose monitor unit rate must be displayed at the treatment control panel;

2. If the equipment can deliver, under any conditions, an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device must be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum.

3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten (10) times the maximum value specified by the manufacturer, a device must be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

4. For each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the maximum value(s) specified in 180 NAC 20-007, item 2. and 3. for the specified operating conditions. Records of these maximum value(s) must be maintained at the installation for inspection by the Department.

20-007.10 Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy

1. Each primary system must terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;

2. If the original design of the equipment included a secondary dose monitoring system, that system must be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. For equipment installed after [INSERT EFFECTIVE DATE OF THESE REGULATIONS], an indicator on the control panel must show which monitoring system has terminated irradiation.

20-007.11 Termination of Irradiation It must be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any

time from the operator's position at the treatment control panel.

20-007.012 Interruption of Irradiation If a therapeutic radiation machine has an interrupt mode, it must be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it must be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements must be automatically terminated.

20-007.013 Timer A suitable irradiation control device must be provided to terminate the irradiation after a pre-set time interval.

1. A timer must be provided which has a display at the treatment control panel. The timer must have a pre-set time selector and an elapsed time indicator;

2. The timer must be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator;

3. The timer must terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

20-007.14 Selection of Radiation Type Equipment capable of both X-ray therapy and electron therapy must meet the following additional requirements:

1. Irradiation must not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

2. The radiation type selected must be displayed at the treatment control panel before and during irradiation;

3. An interlock system must be provided to ensure that the equipment can principally emit only the radiation type that has been selected;

4. An interlock system must be provided to prevent irradiation with X-rays, except to obtain an image, when electron applicators are fitted;

5. An interlock system must be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

6. An interlock system must be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

20-007.15 Selection of Energy Equipment capable of generating radiation beams of different energies must meet the following requirements:

1. Irradiation must not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected must be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it must be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

3. Irradiation must not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

20-007.16 Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy must meet the following requirements:

1. Irradiation must not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

2. The mode of operation must be displayed at the treatment control panel;

3. An interlock system must be provided to ensure that the equipment can operate only in the mode that has been selected;

4. An interlock system must be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

5. Moving beam radiation therapy must be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment installed after [INSERT EFFECTIVE DATE OF THESE REGULATIONS]:

    a. An interlock system must be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or 1 cm of linear motion differs by more than 20 percent from the selected value;

    b. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered must differ by less than 5 percent from the dose monitor unit value selected;

    c. An interlock must be provided to prevent motion of more than 5 degrees or 1 cm beyond the selected limits during moving beam radiation therapy;

    d. An interlock must be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

e. Moving beam radiation therapy must be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation must be as required by 180 NAC 20-007.10; and

7. For equipment installed after the effective date of these regulations, an interlock system must be provided to terminate irradiation if movement:

a. Occurs during stationary beam radiation therapy; or
b. Does not start or stop during moving beam radiation therapy unless such stoppage is a pre-planned function.

20-007.17 Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV In addition to shielding adequate to meet requirements of 180 NAC 20-009, the following design requirements include:

1. Protective Barriers All protective barriers must be fixed, except for access doors to the treatment room or movable beam interceptors;

2. Control Panel In addition to other requirements specified in 180 NAC 20, the control panel must also:

a. Be located outside the treatment room;
b. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;
c. Provide an indication of whether radiation is being produced; and
d. Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine.

3. Viewing Systems Windows, mirrors, closed-circuit television or an equivalent viewing system must be provided to permit continuous observation of the patient following positioning and during irradiation and must be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine must not be used for patient irradiation unless at least one viewing system is operational;

4. Aural Communications Provision must be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine must not be used for irradiation of patients unless continuous two-way aural communication is possible;
5. Room Entrances Treatment room entrances must be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF";

6. Entrance Interlocks Interlocks must be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it must not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

7. Beam Interceptor Interlocks If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 180 NAC 4-013.01 and 4-013.02, interlocks must be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

8. Emergency Cutoff Switches At least one emergency power cutoff switch must be located in the radiation therapy room and must terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 180 NAC 20-007.11. All emergency power cutoff switches must include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch. All emergency cutoff switches must be labeled;

9. Safety Interlocks All safety interlocks must be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine. All interlocks and visible or audible alarms must be tested for proper operation at intervals not to exceed three months; and

10. Surveys for Residual Radiation Surveys for residual activity must be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

20-007.18 Radiological Medical Physicist Support.

1. The services of a Radiological Medical Physicist is required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Radiological Medical Physicist must be responsible for:

   a. Full calibration(s) required by 180 NAC 20-007.20 and protection surveys required by 180 NAC 20-004.01.;
   b. Supervision and review of dosimetry;
   c. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;
   d. Quality assurance, including quality assurance check review required by 180 NAC 20-007.21, item 5.
   e. Consultation with the user in treatment planning, as needed; and
   f. Perform calculations/assessments regarding misadministrations.

2. If the Radiological Medical Physicist is not a full-time employee of the registrant, the operating procedures required by 180 NAC 20-007.19 must also specifically address how the Radiological Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Radiological Medical Physicist can be contacted.

20-007.19 Operating Procedures

1. No individual, other than the patient, must be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

2. Therapeutic radiation machines must not be made available for medical use unless the requirements of 180 NAC 20-004.01, 20-007.20 and 20-007.21 have been met;

3. Therapeutic radiation machines, when not in operation, must be secured to prevent unauthorized use;

4. When adjustable beam limiting devices are used, the position and shape of the radiation field must be indicated by a light field.

5. If a patient must be held in position during treatment, mechanical supporting or restraining devices must be used; and

6. A copy of the current operating and emergency procedures must be maintained at the therapeutic radiation machine control console.

20-007.20 Acceptance Testing, Commissioning and Full Calibration Measurements

1. Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to 180 NAC 20-007 must be performed by, or under the direct supervision of, a Radiological Medical Physicist.

2. Acceptance testing and commissioning must be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45" and must be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

3. Full calibration must include

   a. The calibration of systems subject to 180 NAC 20 must be performed in accordance with the protocol published by the American Association of Physicist in Medicine, or a user submitted protocol having the prior approval of the Department, before the system is first used for irradiation of patients and thereafter at time intervals which do no exceed one year and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.

b. An independent verification by a third part medical physicist other than the person performing the calibration.

4. The Radiological Medical Physicist must perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

a. Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities must require measurements for only those modes and/or energies that are not within their acceptable range; and

b. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements must be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 180 NAC 20-007.20, item 4.a.

5. The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include: the date of the calibration; the manufacturer's name, model number and serial number for the therapeutic radiation machine; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the Radiological Medical Physicist responsible for performing the calibration.

20-007.21 Periodic Quality Assurance Checks

1. Periodic quality assurance checks must be performed on all therapeutic radiation machines subject to 180 NAC 20-007 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40"; or other submitted procedure, having the prior approval of the Department

2. To satisfy the requirement of 180 NAC 20-007.21, item 1., quality assurance checks must include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" or a user submitted protocol having the prior approval of the Department. Representative sampling must include all referenced periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months;

3. The registrant must use a dosimetry system that has been inter-compared within the previous 12 months with the dosimetry system described in 180 NAC 20-

004.03, item 1. to make the periodic quality assurance checks required in 180 NAC 20-007.21, item 2.;

4. The registrant must perform periodic quality assurance checks required by 180 NAC 20-007.21, item 1. in accordance with written procedures established by the Radiological Medical Physicist;

5. The registrant must review the results of each periodic radiation output check according to the following procedures:

   a. The user and Radiological Medical Physicist must be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine must not be made available for subsequent medical use until the Radiological Medical Physicist has determined that all parameters are within their acceptable tolerances;
   b. The Radiological Medical Physicist must review and sign the results of each radiation output quality assurance check at intervals not to exceed 1 month.

6. Therapeutic radiation machines subject to 180 NAC 20-007 must have safety quality assurance checks listed in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40"or a user submitted protocol having the prior approval of the Department performed at intervals not to exceed 1 week;

7. To satisfy the requirement of 180 NAC 20-007.21, item 6., safety quality assurance checks must ensure proper operation of:

   a. Electrical interlocks at each external beam radiation therapy room entrance;
   b. Proper operation of the "BEAM-ON", interrupt and termination switches;
   c. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
   d. Viewing systems;
   e. Electrically operated treatment room door(s) from inside and outside the treatment room;
   f. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch must be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

8. The registrant must promptly repair any system identified in 180 NAC 20-007.21, item 7. that is not operating properly; and
9. The registrant must maintain a record of each quality assurance check required by 180 NAC 20-007.021, item 1. and 7. for 3 years. The record must include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model number and serial number for the instrument(s)

used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

20-008 CALIBRATION OF SURVEY INSTRUMENTS

20-008.01 The registrant must ensure that the survey instruments used to show compliance with 180 NAC 20 have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

20-008.02 To satisfy the requirements of 180 NAC 20-008.01, the registrant must:

1. Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

2. Calibrate at least two (2) points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale; and

20-008.03 To satisfy the requirements of 180 NAC 20-008.02, the registrant must:

1. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

2. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

20-008.04 The registrant must retain a record of each calibration required in 180 NAC 20-008.01 for 3 years. The record must include:

1. A description of the calibration procedure; and

2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

20-008.05 The registrant may obtain the services of individuals licensed by the Department, the U. S. Nuclear Regulatory Commission, or an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations that contain information required by 180 NAC 20-008.04 must be maintained by the registrant.

20-009 SHIELDING AND SAFETY DESIGN REQUIREMENTS

20-009.01 Each therapeutic radiation machine subject to 180 NAC 20-006 or 20-007 must be provided with such primary and/or secondary barriers as are necessary to ensure compliance with 180 NAC 4-005 and 4-013.

20-09.02 Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy must be submitted for Department approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix 20-A.

APPENDIX 20-A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

I. All Therapeutic Radiation Machines.

A. Basic facility information including: name and telephone number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam must have primary barriers.

C. Secondary barriers must be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic Radiation Machines up to 150 Kv (photons only).

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV will submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;

B. Maximum design workload for the facility including total weekly radiation output, [expressed in gray (rad) or air kerma at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;C. A facility blueprint/drawing indicating: scale [0.25 inch = 1 foot is typical]; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth must be noted on the plan and the operator's station at the control panel must be behind a protective barrier sufficient to ensure compliance with 180 NAC 4-005;

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present; and

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s)] and shielding material in the facility:

1. If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date.

2. Submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic Radiation Machines Over 150 kV.

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV and/or electrons must submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced [i.e.: photon, electron]. The target to isocenter distance must be specified;

B. Maximum design workload for the facility including total weekly radiation output [expressed in gray (rad) at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

C. Facility blueprint/drawing [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = 1 foot is typical], type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier [ceiling, walls and floor], as well as details of the door(s) and maze;

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy [i.e.: room may be designed for 6 MV unit although only a 4 MV unit is currently proposed], work-load, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier [walls, floor and ceiling] and expected radiation exposure in both restricted and unrestricted areas; and

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e.: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility:

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date; and

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron Shielding

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities that are capable of operating above 10 MV must submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material;

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas;

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [i.e.: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility:

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date; and

(2) Submit quality control sample calculations to verify the result obtained with the software.D. The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators"

(1984).